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09/549,642	04/14/2000	Johan R. de Faire	314572-101F	9183

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 07/01/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/549,642

Applicant(s)

DE FAIRE ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 142-145 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 142-145 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Status of the Claims*

1. Currently Claims 142-145 are pending in this application. Claims 142-144 were pending and rejected in the prior action, mailed on November 5, 2002. In the Response filed on May 8, 2003, the Applicant amended claim 144, and added claim 145. All of the pending claims are under consideration.
2. Because this action raises a new rejection not made in the prior action, the action is being made Non-Final.

### *Specification*

3. **(Prior Objection-Withdrawn)** The specification is objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). In view of the amendments to the application, this objection is hereby withdrawn.
4. **(Prior Objection- Maintained)** The amendment filed October 3, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The Applicant has amended the specification to avoid this objection in part. See, amendments to pages 35 line 22 - p. 38, line 24. However, the objection is maintained to the extent of the cancellations to the specification at page 2, lines 3-30; page 3, lines 1-9; and to the teachings of Example 1A at page

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40, lines 10-30. These two sections refer 1) to preferred embodiments of the claimed invention, and 2) to methods of preparing the compound used in the claimed methods, and referred to in the specification as such (see e.g., page 69, lines 27-29, and page 70, lines 10-12 (each referring to the method of Example 1A, which was cancelled from the Application.)). Correction is required.

### ***Claim Objections***

5. **(Prior Objection- Withdrawn)** Claim 144 was objected to in the prior action because of the following informality. In line 2 of the claim, the term “not” should read “no.” The error has been corrected by amendment. The objection is therefore withdrawn.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**(Prior Rejection- Maintained)** Claims 142-144 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 143 and 144 describes the limitation to the claimed methods, respectively, as follows: “wherein the dental plaque is visually observable,” and “wherein the contacting is conducted or repeated until dental plaque is no longer visually observable.” There is no support for such open-ended language in the specification. The specification in the application explicitly states that the

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treatment may not continue “for longer than 7 days.” Page 70, lines 16-18. The Applicant traverses the rejection stating, “that the language cited states an exemplary protocol found in one dental plaque example, but not the other.” The other example referred to by the Applicant concludes treatment within four days, and does not state that it may continue indefinitely. In view of the positive statement by the Applicant, that treatment may not continue for more than 7 days, and the lack of any disclosure to the contrary elsewhere in the specification, the rejection is maintained.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **(New Rejection)** Claims 142-144 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 93/24142, naming Lindblom et al. as inventors. The claims describe methods of removing dental plaque from an animal by contacting the plaque with a mixture of krill enzymes. The reference teaches uses of enzymatic protein compositions isolated from krill. Page 1, lines 2-12. Among the uses taught by the reference are for the reduction of dental plaque in animals. Pages 19-20. The two examples provided in the reference teach all of the limitations of the claims. In each case, the level of plaque was determined visually, and the treatments were performed until the plaque is no longer visible. E.g., page 18, line s24-29. Furthermore, the

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reference teaches that the treatment should not be continued for more than seven days. Page 20, lines 11-12. The reference therefore anticipates the rejected claims.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Maintained)** Claims 142-144 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Ratcliff (U.S. Patent 4,837,009), in view of Hellgren (U.S. Patent 4,963,491) and Karlstam (EPA 0257003). The claims read on methods of removing dental plaque from teeth in an animal subject by contacting the plaque with an effective amount of hydrolase mixture comprising krill enzymes. The dependant claims add the limitations that the dental plaque be visually observable, and that the contacting be continued until such time as the plaque is no longer visually observable.

The Applicant traverses this rejection on two grounds. First, the Applicant submits that the rejection is cumulative of the withdrawn rejection over the Hellgren alone. It is assumed that the applicant is suggesting that the present rejection should be withdrawn for the same reason as the withdrawal of the rejection over Hellgren. However, this rejection is not considered by the Examiner to be cumulative of the Hellgren rejection. It was clearly stated in the withdrawal of that rejection was made because "the reference is more properly applicable as [a] reference under

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35 U.S.C. 103(a) in combination with the Ratcliff and Karlstam references.” Thus, the current rejection is not cumulative to, but is a modified form of the withdrawn rejection over Hellgren.

The second traversal of the rejection is on the grounds that the Examiner is inappropriately using hindsight to assert that there would have been a reasonable expectation of success in the combination of the references to arrive at the claimed method. The Examiner is not persuaded by this argument. Even if the teachings of these three references was not sufficient to indicate the efficacy of the krill enzyme composition, the further teachings of the Lindblom reference described above. The rejection is therefore maintained.

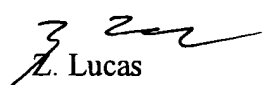
### *Conclusion*


11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Z. Lucas  
Patent Examiner  
June 24, 2003

  
JAMES HOUSEL 6/30/03  
SUPERVISORY PATENT EXAMINER  
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